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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/531,113	03/22/2000	Joseph R. Byrum	38-21(15761)B (16517.001)	4899
27161	7590	10/29/2004	EXAMINER	
MONSANTO COMPANY 800 N. LINDBERGH BLVD. ATTENTION: G.P. WUELLNER, IP PARALEGAL, (E2NA) ST. LOUIS, MO 63167			WILDER, CYNTHIA B	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 10/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/531,113

Applicant(s)

BYRUM ET AL.

Examiner

Cynthia B. Wilder, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 8-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 8-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

FINAL ACTION

1. Applicant's amendment filed August 8, 2004 is acknowledged and has been entered. Claim 1 has been amended. Claims 2-7 have been canceled. Claims 1, 8-13 are pending and discussed below. All of the arguments have been thoroughly reviewed and considered but are not found persuasive for the reasons discussed below. Any rejection not reiterated in this action has been withdrawn as being obviated by the amendment of the claims.

This action is made FINAL

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Previous Rejections

3. The claim rejection under 35 USC 101 directed to claims 1, 8-13 as lacking utility and enablement is maintained and discussed below. The claim rejection under 35 USC 112 first paragraph as lacking written description is withdrawn in view of Applicant's amendment and arguments. The prior art rejection under 35 USC 102(e) as being anticipated by Cohen et al is withdrawn in view of Applicant's amendment and arguments.

Claim Rejections - 35 USC § 101 (Lack of Utility)

4. Once again, claims 1, 8-13 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility.

The claimed subject matter is not supported by a specific; substantial or a well established utility because the disclosed uses are generally applicable to broad classes of this

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subject matter. In addition, further characterization of the claimed subject matter would be required to identify or reasonably confirm a "real world" use.

The claimed invention is drawn to a substantially purified nucleic acid molecule that encodes a soybean protein or fragment thereof comprising a nucleic acid sequence of SEQ ID NO: 5981 or a substantially purified nucleic acid molecule comprising a sequence having between 100% and 90% sequence identity with a nucleic acid sequence of SEQ ID NO: 5981 or complement thereof. As noted earlier, a well-established utility is defined as a specific, substantial and credible utility which is well known, immediately apparent or implied by the specification's disclosure of the properties of the material, alone or taken with the knowledge of one skilled in the art. The specification discloses a number of general utilities for the nucleic acid molecule disclosed herein. For example, the specification discloses that the nucleic acid molecules may be used as molecule tags to isolate genetic regions, isolate genes, map genes and determine gene function (page 15), in marker-assisted breeding programs (page 16), as antibodies (page 16), as primer and probes for the isolation of full length cDNAs or genes (page 28), in mutation detection (page 37), in the identification of polymorphism (page 38), as molecular markers (page 50), genetic mapping studies (page 49), in DNA-protein interaction (page 52) in methods of identifying chromosomes with translocation (page 52), in method of protein-protein interaction (page 60), in microarray based methods (page 54), in site directed mutagenesis (page 56) and in methods of transformation (page 61). None of these asserted utilities are specific because the disclosed uses of the nucleic acids are generally applicable to any nucleic acid and therefore are not particular to the nucleic acid sequence being claimed. Likewise no direct connection is made between the claimed sequence or any of the numerous

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utilities claimed. The examples beginning at page 85 do not provide any disclosure which demonstrates the functionality of the claimed nucleic acid sequence or fragments thereof or complement thereof as for example, probes and/or primers to detect a mutation or as marker to determine gene function. Thus, further research is required to determine the specific utility of the claimed nucleic acid sequence.

Further, the claimed nucleic acid and/or the encoded protein are not supported by a substantially utility because no substantial utility has been established for the claimed subject matter. For example, a nucleic acid may be utilized to obtain a protein. The protein could then be used in conducting research to functionally characterize the protein. The need for such research clearly indicates that the protein and/or its function is not disclosed as to a currently available or substantial utility. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case none of the proteins that are to be produced as final products resulting from processes involving claimed nucleic acid have asserted or identified specific and substantial utilities. The research contemplated by Applicant to characterize potential protein products, especially their biological activities, does not constitute a specific and substantial utility. Identifying and studying the properties of a protein itself or the mechanisms in which the protein is involved does not define a "real world" context or use. Similarly, the claimed use of the nucleic acid the instant specification is neither substantial nor specific due to being generic in nature and applicable to a myriad of nucleic molecules Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed. Neither the specification as filed

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nor any art of record discloses or suggests any property or activity for the nucleic acid or the encoded protein such that another non-asserted utility would be well established for the compounds.

Claims 1-16 and 35-38 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Applicant's Traversal and Examiner's Response to Remarks

5. Applicant traverses the rejections on the following ground(s):

Applicant asserts that the claimed nucleic acid molecules are useful in determining the presence or absence of polymorphism, isolating specific promoter sequences and to obtain nucleic acid homologous (page 6). In response to Applicant's arguments, the Examiner maintains as noted in the utility rejection of the previous Office action that none of these are specific to the claimed nucleic acid molecules and complements thereof as these utilities are generally applicable to the entire class of chemicals known as nucleic acids.

Applicant asserts that many of these uses are directly analogous to the use of a microscope. Applicant states that an important utility of a microscope resides in its use to identify and characterized the structure of biological tissues in a sample, cell or organism. In response to Applicant's argument, it is noted that a microscope has a real world utility in magnifying any object that is set onto the plate under the objective lens. The nucleic acid sequence of SEQ ID NO: 5981 or complements thereof, on the other hand could only be used to examine itself, or nucleic acid very similarly to itself and such an interrogation (in a mapping

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procedure or to determine if there are polymorphic sites within SEQ ID NO: 1) does not provide an immediately useful benefit and thus does not meet the requirements for utility under 35 USC 101.

Applicant asserts that the putative use of the nucleic acid sequence (SEQ ID NO: 5981 or complements thereof as a structural nucleic acid is a legally sufficient utility and argues the new golf analogy (see pages 6 and 7). In regards to Applicant's arguments, the Examiner asserts that this is not found persuasive because the fact that SEQ ID NO: 5981 may encode something is general to all nucleic acid (i.e., non-specific), and the fact that the nucleic acid molecule may encode some protein in particular is not substantial absent some knowledge of the protein and its specific and substantial utility. Applicant's application is an invitation to carry out further experimentation to reasonably confirm a specific, substantial and credible utility for nucleic acids or complements thereof comprising SEQ ID NO: 5981. Further, in addressing the golf club analogy set forth on pages 6 and 7, Applicant is in fact stating that a golf club has a specific utility, that is to hit a golf ball, not any object. This is equivalent to a specific utility for a nucleic acid wherein a nucleic acid is useful detecting a disease state or disease condition. Simply stating that a nucleic acid has utility because it does something that is well recognized in the art (for example, hybridizing to itself) is not specific because this is not a real world utility. There is no reason one would want to detect the instant nucleic acid molecules (SEQ ID NO: 5981 or complement thereof), except to do further research to reasonably confirm a real world utility for the nucleic acid molecule of SEQ ID NO: 5981 or complement thereof.

Applicant argues that one of ordinary skill in the art would recognize that the claimed nucleic acid have utility, for example, to identify polymorphisms and markers and isolate

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promoters in soybean plants upon reading the present specification (page 8). In regards to Applicant's arguments, it is noted that Applicant is setting forth arguments concerning the detection of polymorphism as if polymorphisms within SEQ ID NO: 5891 or complement thereof are known. Even if the determination of the presence or absence of polymorphisms within SEQ ID NO: 5891 in the soybean plant population were specific, substantial and credible utility, this invention could not be practice based on the teachings of the instant specification without further research because no polymorphisms within SEQ ID NO: 5891 are disclosed. In regards to Applicant's arguments concerning isolating promoter regions in the soybean plant, it is noted that the specification does not provide any specific disclosure for the instant molecule of SEQ ID NO: 5981 or any complements thereof. The specification only speculates that the instant invention comprises the general utilities known in the art and as noted earlier, invites one to undertake an unknown amount of research to reasonably confirm that the sequence of SEQ ID NO: 5981 or complement thereof or any other variants of SEQ ID NO: 5891 encompassed within the claims actually is, for example, a promoter or a marker of a phenotype or developmental stage or contains a polymorphism or SNP, etc.

Applicant traverses the enablement rejection for the reasons discussed earlier regarding utility. The examiner maintains the rejection for the same reasons applied regarding utility. For all of the foregoing, the rejections under 35 USC 101 and 35 USC 112 first paragraphs directed to claims 1 and 8-13 are maintained.

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Conclusion

1. No claims are allowed. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be emailed to cynthia.wilder@uspto.gov. Since email communications may not be secure, it is suggested that information in such request be limited to name, phone number, and the best time to return the call.

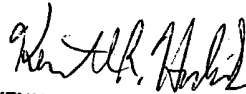
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

10/25/04